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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/797,907	03/09/2004	Duran Yetkinler	SKEL-012CIP	3390

24353 7590 03/09/2007  
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EXAMINER
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RAMANA, ANURADHA

ART UNIT	PAPER NUMBER
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3733

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/09/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

<b>Office Action Summary</b>	Application No. 10/797,907	Applicant(s) YETKINLER ET AL.	
	Examiner Anu Ramana	Art Unit 3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 11 December 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 33-40, 42-45, 47-50, 53 and 54 is/are pending in the application.
- 4a) Of the above claim(s) 48-50 and 53 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 33-40, 42-45, 47 and 54 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 June 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on December 11, 2006 has been entered.

### ***Election/Restrictions***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 33-40, 42-45, 47 and 54, drawn to a method, classified in class 606, subclass 86.
- II. Claims 48-50 and 53, drawn to a kit, classified in class 606, subclass 92.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another and materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case, the apparatus can be used to practice a method in which the penetration of cement does not stop substantially simultaneously with cessation of vibration.

Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required

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because the inventions have acquired a separate status in the art due to their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

During a telephone conversation with the Attorney of Record, Bret E. Field, on February 27, 2007, a provisional election was made to prosecute the invention of Group I, claims 33-40, 42-45, 47 and 54. Affirmation of this election must be made by applicant in replying to this Office action. Claims 48-50 and 53 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 33-40 and 44-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuslich et al. (US 6,620,162) in view of Olson, Jr. et al. (US 2004/0024410).

Kuslich et al. disclose a method of introducing a composition into a target bone site including the step of: delivering a composition or "compound" to a target bone site through an introduction element or needle 14 (Fig. 2, col. 3, lines 42-56, col. 4, lines 41-67, col. 5, lines 22-31 and col. 7, lines 22-27). Note that particles of the compound pass through the needle 14 individually when the Kuslich et al. device is activated. Thus,

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penetration of the compound stops substantially simultaneously with cessation of vibration.

Regarding claims 44 and 45, Kuslich et al. disclose that their method can be used to fill and compact a compound within a portion of a bone, or a fixation device positioned therein (col. 2, lines 63-67). Kuslich et al. also disclose that the fixation device can be an externally threaded, hollow spinal implant or cannulated screw (col. 2, lines 58-60 and col. 3, lines 42-48; see US 5,489,308 incorporated by reference in US 6,620,162).

Kuslich et al. disclose all elements of the claimed invention except for a calcium phosphate composition.

Olson, Jr. et al. teach the use of calcium phosphate particles to fill a void (para [0075]).

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have utilized the method of Kuslich et al. to introduce calcium phosphate particles, as taught by Olson, Jr. et al., since it was well known in the art to utilize media such as calcium phosphate particles to fill a bone void.

Regarding claim 39, the combination of Kuslich et al. and Olson, Jr. et al. discloses all elements of the claimed invention except for the claimed range of vibration frequencies. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have utilized vibration frequencies in a range of 0.1 to 100,000 Hz, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

The method steps of claims 33-40 and 44-45 are rendered obvious by the above discussion.

Claims 33-40, 42-45 and 54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Karpman et al. (US 6,214,012) in view of Constantz et al. (US 6,083,229).

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Karpman et al. disclose the method steps of: positioning a hardware device such as a cannulated screw 30 in conjunction with any number of conventional fixation devices such as wires, plates, rods at a target bone site including cancellous bone; and delivering cement to the target bone site by syringe or cement gun for internal fixation following fracture reduction (Figs. 3 and 4, col. 5, lines 35-67, col. 7, lines 5-29 and col. 9, lines 24-54).

Karpman et al. disclose all elements of the claimed invention except for: (1) a calcium phosphate cement; and (2) vibration of the cement as it is being delivered to the target bone site.

Constantz et al. teach the use of external energy in the form of vibration instead of application of pressure to aid delivery of calcium phosphate bone cement to a target bone site by vibrating a portion of the cement delivery device or the entire cement delivery device (col. 25, lines 15-59, col. 27, lines 31-57, col. 28, lines 15-67, col. 29 and col. 30, lines 1-38). Note that since the driving force is vibration, delivery of cement would stop substantially simultaneously with cessation of vibration, i.e., removal of the driving force.

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have vibrated the Karpman et al. cement delivery device, as taught by Constantz et al., to promote efficient filtration of the calcium phosphate cement composition through the target bone site.

Regarding claim 39, the combination of Karpman et al. and Constantz et al. discloses all elements of the claimed invention except for the claimed range of vibration frequencies. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have utilized vibration frequencies in a range of 0.1 to 100,000 Hz, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

The method steps of claims 33-40, 42-45 and 54 are rendered obvious by the above discussion.

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Claim 47 is rejected under 35 U.S.C. 103(a) as being unpatentable over Karpman et al. (US 6,214,012) and Constantz et al. (US 6,083,229) further in view of Bakels et al. (US 4,787,751).

The combination of Karpman et al. and Constantz et al. discloses all elements of the claimed invention except for preparing the cement composition in conjunction with vibration.

Bakels et al. teach preparing bone cement utilizing vibration to deaerate the cement (col. 1, lines 6-9, lines 24-28 and lines 35-43, col. 2, lines 30-68 and col. 5, lines 3-16).

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have vibrated the cement used in the method of combination of the Karpman et al. and Constantz et al., as taught by Bakels et al., to deaerate the cement.

The method steps of claim 47 are rendered obvious by the above discussion.

### ***Response to Arguments***

Applicant's arguments with respect to claims 33-40, 42-45, 47 and 54 have been considered but are moot in view of the new ground(s) of rejection.

### ***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anu Ramana whose telephone number is (571) 272-4718. The examiner can normally be reached Monday through Friday between 8:00 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached at (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AR  
March 3, 2007

A handwritten signature in black ink, reading "Anuradha Kamara". The signature is written in a cursive style with a large, looping initial 'A'.